UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,059	12/29/2003	Kevor Tenhuisen	ETH-5119	8329

27614 7590 08/01/2008

MCCARTER & ENGLISH, LLP
FOUR GATEWAY CENTER
100 MULBERRY STREET
NEWARK, NJ 07102

EXAMINER	
DORNBUSCH, DIANNE	

ART UNIT	PAPER NUMBER
3773	

MAIL DATE	DELIVERY MODE
08/01/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/748,059	TENHUISEN ET AL.	
	Examiner	Art Unit	
	DIANNE DORNBUSCH	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claim 1-4, 6, and 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Mikus et al. (2002/0151967).

Mikus discloses the following claimed limitations:

Claim 1: An apparatus for compressing a stent having at least one protrusion, comprising: a mandrel (114) insertable into a lumen of the stent (110) for holding the stent (Fig. 14); a protrusion compressor (115) coupled to said mandrel (114) (Fig. 4), said mandrel (114) rotatable relative to said protrusion compressor (115) ([0087] Lines 10-11), said protrusion compressor (115) having a tab (the hook in Fig. 14) extending therefrom towards said mandrel (114), said tab (the hook seen in Fig. 14 is pressing on one protrusion of the stent) pressing the at least one protrusion of the stent inwardly toward the lumen of the stent when said mandrel is rotated relative to said protrusion compressor ([0096] Lines 8-12 where as the rotation is making the stent expand it can also make it contract).

Claim 2: That said mandrel (114) extends through said protrusion compressor coaxially (Fig. 13-14).

Claim 3: That the apparatus further comprising a knob (117) disposed on an end of said mandrel (114) to aid in turning said mandrel (114) and for retaining said protrusion compressor (115) on said mandrel ([0096] Lines 9-10).

Claim 6: That said protrusion compressor (115) is captured between said knob (117) and said stent retention zone (112) as seen in Fig. 14.

Claim 13: An apparatus for compressing a coiled stent (110) having at least one external protuberance, comprising: means for holding the stent (112 which is the stent segment, with gap/hook 127 of component 114 seen in Fig. 14); means for compressing (115) the at least one external protuberance (the hook seen in Fig. 14 is pressing on one protrusion of the stent), said means for compressing (115) being rotatably coupled to said means for holding (114) ([0087] Lines 10-11), such that relative rotation thereof compresses the at least one protuberance ([0096] Lines 8-12 where as the rotation is making the stent expand it can also make it contract), said means for compressing (115) acting on the stent by exerting a force (by using the hook in seen in Fig. 14) perpendicular to an axis of the stent (compresses it inwardly by pressing on it).

Claim 14: That the apparatus further comprising, means for gripping (117) said means for holding (114) the stent (110) to aid in rotating said means for holding relative to said means for compressing (115) ([0096] Lines 9-10).

Claim 15: The apparatus further comprising, means for gripping (118) said means for compressing the stent (115).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claim 4, 7, 8, and 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mikus et al. (2002/0151967).

Claim 4:

Mikus discloses that said mandrel (114) has a stent fixation zone (112) with an outer diameter approximating the interior diameter of at least a portion of the lumen of the stent ([0089] Lines 1-5) and frictionally engaging the stent (110) when the stent (110) is placed on the mandrel (114) over the stent retention zone (112). The stent is placed on the mandrel where it has to have frictional engagement since both parts are touching each other as seen in Fig. 13.

Mikus discloses the claimed invention except for the stent fixation zone having an outer diameter greater than the interior diameter of a portion of the lumen of the stent prior to installation of the stent on the mandrel. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have a slightly greater diameter, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

Claim 7:

Mikus discloses that said protrusion compressor (115) has a grip portion (the proximal end of 115 can be used to grip the device) with a hub (137) and a collar (118), and having said tab (the hook in Fig. 14) extending therefrom at a distal end thereof (Fig. 14). The hub (137) is used to lock the mandrel and the compressor longitudinally in relation to each other until longitudinal movement is desired. When movement is desired, the hub is easily removable, and is provided with a longitudinal slit to permit easy removal by the operator during surgery.

Mikus teaches all the claimed limitations discussed above however, Mikus does not disclose in this embodiment that the collar restrained from rotating relative to said grip portion by a pin extending there through and into an elongated slot in said hub.

Mikus in a second embodiment of the device discloses a pin (210, 236) that prevents movement ([0103] Lines 5-7) and that the pin is placed on a slit ([0106] Lines 8-9). The examiner would like to note that element 202 is analogous to the hub and collar of the first embodiment (element 137 and 118).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Mikus with a pin that restrict movement in view of the teachings of the second embodiment of Mikus, in order to prevent movement of the device that would cause the accidental deployment of the stent.

Furthermore, Mikus discloses the claimed invention except that said collar coaxially received on said hub instead of said hub (137) coaxially received on said collar (118) as seen in Fig. 14. This is an obvious rearrangement of parts therefore it would

have been obvious to a person with ordinary skill in the art to switch the location of the collar and the hub since it is a matter of rearrangements of parts.

Claim 8: Mikus discloses that said collar (118) has a flange (extending portion in Fig. 14) extending outwardly therefrom for a user to grip said collar (118) to aid in deployment and retraction of said tab (Fig. 14 and [0087] Lines 14-15).

Claim 10:

Mikus discloses that the apparatus further includes a rotational inhibitor disposed between said grip portion (proximal end of 115) and said collar (118), said rotational inhibitor controlling the relative rotation ([0087] the last 5 lines). The rotational inhibitor can be different kinds of locking mechanisms such as a keyway structure.

Mikus teaches all the claimed limitations discussed above however, Mikus does not disclose the apparatus includes a ball and detent interface.

The ball and detent interface is well known in the art as a useful locking mechanism which can be use to inhibit the rotation of the device. Therefore it would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Mikus with a ball and recess mechanism in order to inhibit the rotation of the device as well as a locking mechanism to prevent an early deployment of the stent.

Claim 11: Mikus discloses different kinds of stents that can be used with the device. One such stent is stent 10 which has the at least one protrusion of the stent (33 and 54) is at least one enlarged coil (33 and 54 in Fig. 8) disposed at an end of the stent (Fig. 8). It would have been obvious to a person having ordinary skill in the art at the time the

invention was made to add the coil (33 and 54) on stent 10 (and stent 110) in order to prevent the deployed stent in the urethra from obstructing the sphincter.

Claim 12: The apparatus further including a sleeve (116) extending from said collar (118) distal to said flange (Fig. 14), said tab (the hook in Fig. 14) extending from said sleeve (116). The tab extends from the sleeve as seen in Fig. 14 where it is distally from the distal end of the sleeve (116).

5. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mikus et al. (2002/0151967) in view of Frantzen (6,042,606).

Mikus teaches all the claimed limitations discussed above however, Mikus does not disclose that said mandrel has a tapered end.

Frantzen discloses that said mandrel (M) has a tapered end (T in Fig. 11) (Col, 9 Lines 65-67).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Mikus with the tapered mandrel in view of the teachings of, in order to ease the placement of the stent on the mandrel by sliding the stent through the tapered portion.

Allowable Subject Matter

6. Claim 9 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

7. The following is a statement of reasons for the indication of allowable subject matter: the art of record when considered alone or in combination neither renders

obvious that at least one protrusion of the stent is between the tab and the relief slot when the apparatus compresses the stent protrusion.

Response to Arguments

8. Applicant's arguments filed May 6, 2008 have been fully considered but they are not persuasive.

9. Regarding to the argument that the reference does not show that the tab is pressing the at least one protrusion of the stent inwardly which would exert a force perpendicular to the axis of the stent as stated by applicant in page 4-6 of the argument. The examiner respectfully disagrees with the applicant, since as seen in Fig. 15-16, the proximal portion of the stent is diagonal which indicates that there is a force pushing inwardly at one corner which makes the proximal portion of the stent angled. Additionally, the applicant argues that the tab (the hook in Fig. 14) is actually placed in between the stent and not on top of the stent (the applicant refers to Fig. 13). The examiner disagrees and would like to note that Fig. 13 is a cross section that does not show the entire body of the device. The examiner interprets that portion of the part 115 as being the distal end of the hook which is between the stent segments, but there is still a section of the hook that is shown to be on top of the stent as seen in Fig. 14. The distal end of the hook is still on top of a portion of the stent since it is pushing the proximal end of the stent into an angled position which means it is pushing it inwardly with a force perpendicular to the axis of the stent.
In addition, Fig. 21 and 31 shows that the distal end of the part 115 is on top of a portion of the stent, where the distal end can be the tab (or hook).

10. Regarding the applicant's use of U.S. Patent No. 6,413,269 of Bui et al. to show that the hook is not on top of the stent. The examiner sees that on Fig. 3, the hook of part 15 is still on top of a portion of the stent and that Fig. 2 is also a cross section similar to the cross section referred to above.

11. Regarding to applicant's arguments of claim 7, the examiner disagrees since the element 202 is analogous to parts 137 and 118 of the first embodiment. Element 202 of the second embodiment receives the pin and contains the hole for the pin.

12. Applicant's arguments with respect to claims 4 and 5 have been considered but are moot in view of the new ground(s) of rejection.

13. Applicant's arguments, see the last paragraph of page 8 of the arguments, filed May 6, 2008, with respect to claim 9 have been fully considered and are persuasive. The rejection of claim 9 has been withdrawn.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANNE DORNBUSCH whose telephone number is (571)270-3515. The examiner can normally be reached on Monday through Thursday 7:30 am to 5:00 pm Eastern.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. D./
Examiner, Art Unit 3773

/Julian W. Woo/
Primary Examiner, Art Unit 3773